STATUTORY INSTRUMENTS

2001 No. 880

The Biocidal Products Regulations 2001

PART I

GENERAL

Citation and commencement

1. These Regulations may be cited as the Biocidal Products Regulations 2001 and shall come into force on 6th April 2001.

Interpretation

2.—(1) In these Regulations—

"the 1974 Act" means the Health and Safety at Work etc. Act 1974;

"the 1994 Regulations" means the Chemicals (Hazard Information and Packaging for Supply) Regulations 1994(**1**);

"active substance" means a substance or micro-organism having a general or specific action on or against harmful organisms;

"approved supply list" has the same meaning as it has in the 1994 Regulations;

"biocidal product" means an active substance or a preparation containing one or more active substances, in the form in which it is supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by chemical or biological means;

"classified" means classified in accordance with regulation 5 of the 1994 Regulations and "classification" shall be construed accordingly;

"the Commission" means the Commission of the European Communities;

"Commission decision" means a decision taken in accordance with the procedures set out in Article 28(2);

"competent authority" means the authority appointed in a member State for the purpose of carrying out the duties of a competent authority under the Directive;

"the Directive" means Directive 98/8/EC of the European Parliament and the Council of 16th February 1998 concerning the placing of biocidal products on the market(**2**);

"existing active substance" means an active substance which was on the market in the European Community before 14th May 2000 for a purpose other than process-orientated research and development or scientific research and development;

"feedingstuff" means feedingstuff for animals, birds or fish;

(**1**) S.I.1994/3247, amended by S.I. 1996/1092, 1997/1460, 1998/494, 1998/3106, 1999/197, 1999/3165, 1999/3194, 1999/3232 and 2000/2381.
(**2**) OJ No. L123, 24.4.98, p. 1.

"harmful organism" means an organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment;

"letter of access" means a document—

(a) permitting the use by the Ministers of information, which is—

(i) subject to the provisions of regulation 23 or 24, and

(ii) specified in that document; and

(b) signed by the owner of that information;

"low-risk biocidal product" means a biocidal product—

(a) which does not contain any active substance other than an active substance included only in Annex IA; and

(b) which does not contain a substance of concern; and

(c) which, under the conditions subject to which that biocidal product may be used, poses a low risk to humans, animals and the environment;

"member State" means a member State of the Communities, except the United Kingdom;

"micro-organism" includes a fungus and a virus;

"new active substance" means an active substance which is not an existing active substance;

"placing on the market" means—

(a) any supply, whether in return for payment or not, within Great Britain, including importation into Great Britain; or

(b) any subsequent storage,

other than a supply for storage followed by consignment from the customs territory of the European Community or followed by disposal, and "place on the market", "placed on the market" and "on the market" shall be construed accordingly;

"preparation" means a mixture or solution of two or more substances;

"process-orientated research and development" means the further development of a substance or preparation in the course of which pilot plant or production trials are used to test the fields of application of that substance or preparation;

"product-type" means one of the product-types specified in column 1, and described in column 2, of Schedule 1;

"residue" means a substance present in a biocidal product which remains as a result of the use of that biocidal product, including the metabolites of, and products resulting from the degradation or reaction of, such a substance;

"scientific research and development" means scientific experimentation, analysis or chemical research carried out under controlled conditions including the determination of intrinsic properties, performance and efficacy as well as scientific investigation relating to product development;

"Scotland" has the same meaning as it has in the Scotland Act 1998(**3**).

"substance" means a chemical element and its compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition; and

(**3**) 1998 c. 48.

"substance of concern" means a substance, other than an active substance, which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present in or produced in a biocidal product in sufficient concentrations to create such an effect.

(2) In the application of these Regulations—

(a) subject to sub-paragraph (b) of this paragraph, "the Ministers" means the Secretary of State and the Minister of Agriculture, Fisheries and Food, acting jointly;

(b) in or as regards Scotland, "the Ministers" means the Secretary of State and the Scottish Ministers, acting jointly, and the expression "the Ministers in or as regards Scotland" shall be construed accordingly.

(3) In these Regulations, any requirement to submit or provide information, including information comprising, or included in, a dossier, in support of an application for the authorisation or the registration of a biocidal product under these Regulations, may be satisfied in whole or in part by—

(a) the submission of a letter of access in respect of that information; or

(b) a reference to information which the Ministers or a competent authority already hold and which, by virtue of regulation 23 or 24, the Ministers or the competent authority are entitled to use for the benefit of persons other than the persons who submitted that information.

(4) In these Regulations, a reference to frame-formulation is a reference to specifications for a group of biocidal products which—

(a) have the same use;

(b) are used by the same type of user; and

(c) contain the same active substances of the same specification,

and whose composition, when compared, subject to paragraph (5), with the composition of a biocidal product which has been authorised or registered in accordance with these Regulations, is the same as the composition of that biocidal product.

(5) In carrying out the comparison referred to in paragraph (4), there shall be disregarded a variation which does not reduce the efficacy of, nor affect the level of risk associated with, the biocidal products in question.

(6) In paragraph (5), "variation" means one or more of the following, that is to say—

(a) a lower percentage of each active substance;

(b) a change in the percentage of each substance which is not an active substance;

(c) the replacement of pigments, dyes or perfumes by other pigments, dyes or perfumes having the same or a lower risk.

(7) In these Regulations, any reference to the name of an active substance is a reference to—

(a) the name of that active substance as listed in Part I of the approved supply list; or

(b) if the name is not listed in Part I of the approved supply list, the name of that substance as given in the European Inventory of Existing Chemical Substances(**4**); or

(c) if the name—

(i) is not listed in Part I of the approved supply list, nor

(ii) given in the European Inventory of Existing Chemical Substances,

the International Organisation for Standardisation common name of that active substance; or

(d) if the name—

(**4**) A copy of the European Inventory of Existing Chemical Substances may be obtained from the European Communities Information Office, 8 Storey's Gate, London SW1P 3AT.

(i) is not listed in Part I of the approved supply list, nor

(ii) given in the European Inventory of Existing Chemical Substances,

and there is no International Organisation for Standardisation common name for that active substance, the chemical designation of that active substance according to International Union of Pure and Applied Chemistry rules.

(8) In paragraph (7),

(a) "International Organisation for Standardisation" means the institution of that name founded in 1947 and currently having its headquarters at 1 rue de Varembé, CP56, 1211 Geneva 20, Switzerland; and

(b) "International Union of Pure and Applied Chemistry" means the institution of that name founded in 1919 and currently having its headquarters at Bank Court Chambers, 2-3 Pound Way, Templars Square, Cowley, Oxford OX4 3YF.

(9) In these Regulations, a reference to a biocidal product which contains an active substance shall include a reference to a biocidal product which is an active substance.

(10) In these Regulations, unless the context otherwise requires—

(a) a reference to a numbered regulation or Schedule is a reference to the regulation or Schedule in these Regulations so numbered;

(b) a reference to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule in which that reference occurs; and

(c) a reference to a numbered Article or Annex is a reference to the Article in or Annex to the Directive so numbered.

Application

3.—(1) These Regulations shall not apply to a biocidal product where and to the extent that the biocidal product is placed on the market or used for a purpose over which control is exercised under—

(a) any of the Regulations set out in Schedule 2;

(b) Council Regulation (EEC) No. 2309/93(**5**), laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products; or

(c) sections 32 to 39 or section 58B of the Medicines Act 1968(**6**).

(2) Subject to Schedule 13, these Regulations, except regulation 29, shall not apply to a biocidal product which contains an existing active substance.

(3) These Regulations shall not apply to a biocidal product which is a relevant plant protection product where and to the extent that that biocidal product is placed on the market or used for a purpose over which, but for the provisions of Schedule 3 to the 1995 Regulations, control under the 1995 Regulations would otherwise be exercisable.

(4) These Regulations shall not apply to a biocidal product which, by virtue of regulation 19(1) of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**7**), continues to have a product licence under section 7 of the Medicines Act 1968 so long as that licence remains in force.

(**5**) OJ No. L214, 24.8.93, p. 1.
(**6**) 1968 c. 67; section 58B was added by the Medicines Act 1968 (Amendment) (No. 2) Regulations 1992 (S.I. 1992/3271).
(**7**) S.I. 1994/3142, to which there are amendments not relevant to these Regulations.

(5) These Regulations shall not apply to the placing on the market of a biocidal product prepared extemporaneously in the circumstances described in regulation 5(1)(c) of the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(**8**).

(6) Regulations 30 to 32 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

(7) These Regulations shall not extend to Northern Ireland.

(8) In this regulation—

(a) "the 1995 Regulations" means the Plant Protection Products Regulations 1995(**9**); and

(b) "relevant plant protection product" shall have the meaning assigned to it in paragraph 8 of Schedule 3 to the 1995 Regulations.

(**8**) S.I. 1994/2987, to which there are amendments not relevant to these Regulations.
(**9**) S.I. 1995/887, as amended by S.I. 1997/7, 1997/2499, 1999/3430.